

REMARKS

The Amendment, filed in response to the Office Action mailed May 27, 2010, is believed to fully address all and every issue raised in the Office Action. Favorable reconsideration of the merits and allowance of the application are respectfully requested.

Disposition of Claims

Claims 1-8 are all the claims pending in the application. All claims have been considered and rejected.

In the instant Amendment, claim 1 is amended to define the ratio of methacrylic acid-ethylacrylate copolymer and sucrose fatty acid ester, and more clearly set forth that the methacrylic acid-ethylacrylate copolymer coats the drug. Support for the amendment may be found at, for example, page 4, lines 24-28 of the specification as filed.

No new matter is introduced. Entry and consideration of the Amendment are respectfully requested.

Response to Rejections

In the Office Action, the rejection of claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over Woo, US 6107290, 22 August, 2000 in view of Deutsch, US 4897270, 30 January, 1990 and Alavi, JPharmPharmaceutSci, 5(3), 2002, pp. 234-244 is maintained.

In the Office Action, the rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Woo in view of Deutsch and Alavi, and further in view of Murakami, US 3867414, 18 February, 1975 is maintained.

In the Office Action, the rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Woo in view of Deutsch, Alavi, and Murakami, and further in view of James, US 4865851, 12 September, 1989 is maintained.

Applicant respectfully traverses for the following reasons.

Currently amended claim 1 recites:

A cefuroxime axetil granule composition comprising a non-crystalline cefuroxime axetil solid dispersion or a substantially amorphous cefuroxime axetil, a sucrose fatty acid ester, a methacrylic acid-ethylacrylate copolymer, and a disintegrating agent,

wherein the methacrylic acid-ethylacrylate copolymer and the sucrose fatty acid ester are present at a ratio of 1: 0.5 – 1.5 by weight and wherein the methacrylic acid-ethylacrylate copolymer coats the cefuroxime axetil.

Applicant respectfully submits that none of the cited references teach the recited mixing ratio of the sucrose fatty acid ester and the methacrylic acid-ethylacrylate copolymer. Neither do they suggest or provide guidance to modify their teachings to reach the claimed granule composition, wherein the sucrose fatty acid ester and the methacrylic acid-ethylacrylate copolymer are mixed at the recited ratio.

Methacrylic acid-ethacrylate copolymer alone does not melt for the purpose of preparing a cefuroxime axetil granule composition as desired in the art, but it melts when it is combined with a sucrose fatty acid ester at the claimed mixing ratio, facilitating the methacrylic acid-ethacrylate copolymer (in mixed with sucrose fatty acid ester) can be used to efficiently coat particles of a drug component. Page 4, lines 24-28 of the specification. Also, Fig. 1(c) of the instant application, which is a DSC scan graph of a mixture of sucrose fatty acid ester and methacrylic acid-ethylacrylate copolymer, shows a single absorption peak, indicating that eutectic melting of the ingredients.

On the contrary, the cited references fail to disclose such technical feature of the subject invention. Specifically, although Alavi employs sucrose stearate and Eudragit together, sucrose stearate was used as a droplet stabilizer and localized at the interface between the dispersed phase coated with Eudragit and the dispersion medium. Accordingly, the sucrose stearate is not mixed with Eudragit, and therefore, the unique weight ratio of the methacrylic acid-ethacrylate copolymer and the sucrose fatty acid ester of the subject invention cannot be easily derived from Alavi.

Therefore, Applicant respectfully, but strongly submits that the rejections are not sustainable and withdrawal is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

AMENDMENT UNDER 37 C.F.R. § 1.114(c)
U.S. Application No.: 10/584,919

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Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number **202-775-7588**.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sunhee Lee/

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

Sunhee Lee
Registration No. 53,892

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

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